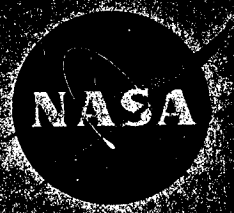
NHB 5340.2
AUGUST 1967
EDITION

NASA STANDARDS FOR CLEAN ROOMS AND WORK STATIONS FOR THE MICROBIALLY CONTROLLED ENVIRONMENT



Per Headquarters, This NHB was cancelled & stated as "OBSOLETE" on Jan 1988.

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National Aeronautics and Space Administration, Washington, D.C. 20546

PREFACE

August 1967

The application of technology related to the exploration of space, the Moon, and the planets of the solar systems has resulted in increased sophistication for components and systems related to space flight hardware. This sophistication has brought with it many new requirements, one of which is the demand for new standards of cleanliness for the fabrication, testing, and launch environment of spacecraft. The policy for the United States space effort is directed toward preventing widespread or excessive biological contamination during exploration of the Moon and assure with a certainty of 0.999 that viable terrestrial organisms will not be transported to other planets until sufficient information has been obtained to insure that biological studies will not be jeopardized and that no hazard to Earth exists. Facilities providing the environmental control necessary for this degree of cleanliness are known as bioclean rooms, bioclean work stations, aerosol particulate controlled facilities, and microbially controlled facilities. Thus, a bioclean room or bioclean work station may be: "A space in which airborne contamination, temperature, humidity, and microbial flora are controlled to a far greater degree than for conventional air conditioned areas."

The issuance of Federal Standard 209a on August 10, 1966, provided the basic document for standard classes of environmental air control within clean rooms and clean work stations; however, control of microbial flora was considered a special environmental condition for which a separate standard should be developed by the agency concerned with this problem. In recognition of this need for standardization of the definitions and degrees of biological environmental control, the National Aeronautics and Space Administration has issued this document. This issuance augments the Design Criteria and Construction Standards (NPC 325-1) with respect to the design and construction of clean rooms and work stations for the microbially controlled environment.

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1. SCOPE

1.1 SCOPE. This document establishes standard classes of air conditions within clean rooms and clean work stations for the microbially controlled environment.

1.2 OBJECTIVE. The objective of this standard is to prescribe air cleanliness classes and certain other conditions required to achieve and maintain the degree of microbial cleanliness specified for the spacecraft and its components from manufacture through launch.

2. REFERENCED DOCUMENTS

2.1 NONGOVERNMENTAL. The following documents, of the issues in effect on the date of invitation for bids, form a part of this standard to the extent specified herein.

AMERICAN SOCIETY FOR TESTING AND MATERIALS:

ASTM F25-63T--Tentative Method For Sizing and Counting Airborne Particulate Contamination in Clean Rooms and Other Dust Controlled Areas Designed For Electronic And Aerospace Work

ASTM F50-65T--Tentative Method Of Test For Continuous Counting And Sizing Of Airborne Particles By The Light Scattering Principle Designed for Electronic and Similar Applications.

(Requests for copies should be submitted to the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.)

SOCIETY OF AUTOMOTIVE ENGINEERS, INCORPORATED:

SAE-ARP-743--Procedure For The Determination Of Particulate Contamination Of Air In Dust Controlled Spaces By the Particle Count Method.

(Requests for copies should be submitted to the Society of Automotive Engineers, Incorporated, 485 Lexington Avenue, New York, New York 10017.)

2.2 GOVERNMENTAL. The following documents of the issues in effect on the date of invitation for bids, form a part of this standard to the extent specified herein.

NPD 8020.7--Certification of the Biological Loading On Outbound Spacecraft

NPD 8020.8--Outbound Lunar Biological Contamination Control; Policy and Responsibility

NHB 5340.1--Standard Procedures For The Microbiological Examination of Space Hardware

(Requests for copies should be submitted to the National Aeronautics and Space Administration (Attention: Code DHA-11), Washington, D.C. 20546.)

3. DEFINITIONS

3.1 BIOCLEAN ROOM. A bioclean room is any enclosed area where there is control over viable and non-viable particulates in air with temperature, humidity, and pressure control as required to maintain specified standards for the manufactured product.

3.2 BIOCLEAN WORK STATION. A bioclean work station is a work bench or similar working enclosure characterized by having its own filtered air or gas supply where there is control over viable and non-viable particulates in air with temperature, humidity, and pressure control as required to maintain specified standards for the manufactured product.

3.3 PARTICLE SIZE. Particle size is expressed as the apparent maximum linear dimension or diameter of the particle.

3.4 MICRON. A unit of measurement equal to one-millionth of a meter (approximately 0.00004 inch). (e.g., 25 microns are approximately 0.001 inch.)

3.5 VIABLE PARTICLE. A particle which will reproduce to form observable colonies when placed on a specified culture medium and incubated according to optimum environmental conditions for growth after collection by methods specified in NHB 5340.1 or revisions thereof.

3.6 NON-VIABLE PARTICLE. A particle which will not reproduce to form observable colonies when placed on a specified culture medium and incubated according to optimum environmental conditions for growth after collection by methods specified in NHB 5340.1 or revisions thereof.

4. GENERAL REQUIREMENTS

4.1 BIOCLEAN ROOM OR BIOCLEAN WORK STATION AREA. These areas shall be operated with emphasis on minimizing airborne viable and non-viable particle generation or concentrations to levels within the limitations indicated in paragraph 5.1 by cleaning the air environment and minimizing product contamination exposure.

4.2 EQUIPMENT CALIBRATION. Equipment used to control, monitor, and record bioclean room and work station conditions shall be calibrated as specified by the manufacturer or in accordance with specifications for the product to be controlled.

4.3 ENVIRONMENTAL CONTROL. Environmental conditions such as temperature, humidity, pressure differential, and viable and non-viable airborne particle count shall be controlled, recorded, and records reviewed as specified for the product to be controlled.

4.4 BIOCLEAN ROOM AIR PRESSURE. Bioclean rooms shall maintain a static air pressure above that of surrounding areas sufficient to assure that it will be in excess of ambient static and velocity head air pressures in these areas and that all leakage is outward.

4.5 AIR CHANGE RATE OR AIR FLOW. Either the air change rate or the air flow shall be specified.

4.6 TEMPERATURE RANGE. The temperature range shall be established as required by the spacecraft product and in consideration of the comfort of personnel occupying the area.

4.7 HUMIDITY RANGE. The maximum relative humidity shall be standardized at $45\%^{+0\%}_{-5\%}$ at the

temperature control point, unless otherwise specified for product control.

4.8 AUDIO NOISE LEVEL. The audio noise level limit allowable shall be specified in accordance with requirements for personnel comfort and pertinent occupational health regulations.

4.9 VIBRATION. The amount and character of allowable vibration shall be specified for the operations to be performed within the facilities.

4.10 MICROBIAL CONTAMINATION. The amount of allowable microbial contamination shall be specified for the operations to be performed within the facility and the procedures for meeting this specification shall be referenced.

4.11 OTHER ENVIRONMENTAL FACTORS. Consideration shall be given to other environmental factors required for personnel comfort and product control. Examples are light level, electromagnetic radiation or field, conduction, radiation, ionizing radiation, radioactive particles, electrostatic charge, gases or vapors.

5. DETAILED REQUIREMENTS

5.1 AIR CLEANLINESS CLASSES. The three classes as defined by this standard are shown in Table I. Classifications are based on total (viable and nonviable) particle count with the maximum allowable number of particles per unit volume or horizontal surface area specified for each class. Special classifications may be used for particle count levels where special conditions dictate their use. Such classes shall be defined by the intercept point on the 0.5 micron line in Table II with a curve parallel to the three established curves.

TABLE I - AIR CLEANLINESS CLASSES

Class English System (Metric System)	Maximum Number of Particles per Cu. Ft. 0.5 micron and Larger (per liter)	Maximum Number of Particles per. Cu. Ft. 5 microns and Larger (per liter)	Maximum Number of Viable Particles per Cu. Ft. (per liter)	Average Number of Viable Particles per Sq. Ft. per Week (per M^2 per week)
100 (3.5)	100 (3.5)	See Note 1 Table II	0.1 (0.0035)	1,200 (12,900)
10,000 (350)	10,000 (350)	65 (2.3)	0.5 (0.0176)	6,000 (64,600)
100,000 (3,500)	100,000 (3,500)	700 (25)	2.5 (0.0884)	30,000 (323,000)

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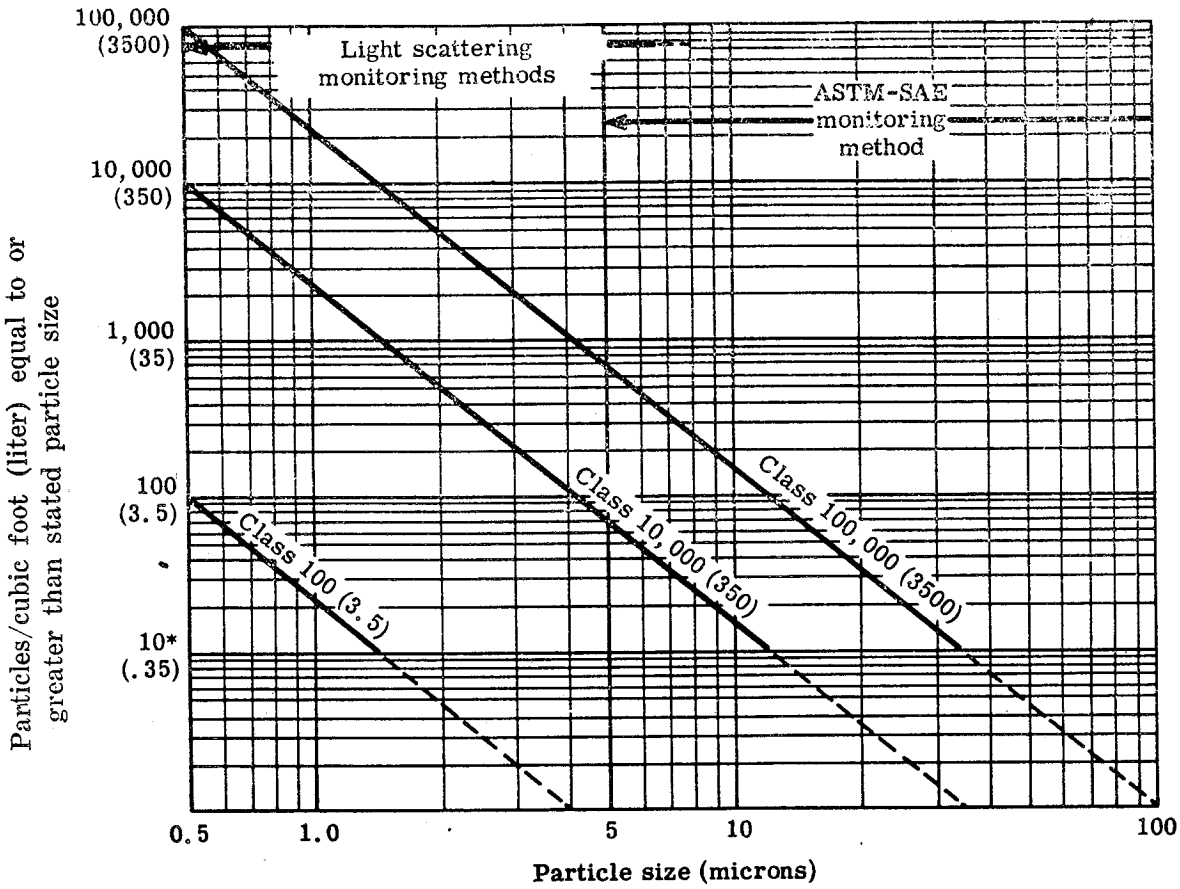
Table II Statistical Average Particle Size Distribution Curves



*Note I: Counts below 10 (0.35) particles per cubic foot (liter) are unreliable except when a large number of samplings is taken.

5.1.1 CLASS 100 (3.5). Particle count not to exceed a total of 100 particles per cubic foot (3.5 particles per liter) of a size 0.5 micron and larger, and a viable particle count not to exceed 0.1 per cubic foot (0.0035 per liter) with an average value not to exceed 1,200 per square foot (12,900 per square meter) per week on horizontal surfaces.

5.1.2 CLASS 10,000 (350). Particle count not to exceed a total of 10,000 particles per cubic foot (350 particles per liter) of a size 0.5 micron and larger, 65 particles per cubic foot (2.3 particles per liter) of a size 5.0 microns and larger, and a viable particle count not to exceed 0.5 per cubic foot (0.0176 per liter) with an average value not to exceed 6,000 per square foot (64,600 per square meter) per week on horizontal surfaces.

5.1.3 CLASS 100,000 (3,500). Particle count not to exceed a total of 100,000 particles per cubic foot (3,500 particles per liter) of a size 0.5 micron and larger, 700 particles per cubic foot (25 particles per liter) of a size 5.0 microns and larger, and a viable

particle count not to exceed 2.5 per cubic foot (0.0884 per liter) with an average value not to exceed 30,000 per square foot (323,000 per square meter) per week on horizontal surfaces.

5.1.4 STATISTICAL AVERAGE PARTICLE SIZE DISTRIBUTION. The three classes of bioclean rooms and work stations are depicted by the statistical average particle size distribution curves in Table II. While the definitions of these classes are taken from these curves, it should be recognized that single sample distributions may deviate from these curves because of local or temporary conditions.

5.2 AIRBORNE PARTICLE MONITORING

5.2.1 PARTICLE COUNTING METHODS. For proof of meeting the requirements of the class of bioclean room or bioclean work station, one or more of the following particle counting methods shall be employed on the site of use:

(a) For particles 0.5 micron and larger, equipment employing light scattering principles shall be used, as specified in ASTM F50.

(b) For particle sizes 5.0 microns and larger, microscopic counting of particles collected on a membrane filter through which a sample of air has been drawn, may be used, as specified in ASTM F25-63T and SAE-ARP-743.

(c) For viable particulates in air flow streams, equipment employing an orifice or slit directly above a sterilized solid nutrient collection medium shall be used as described in "Standard Procedures for the Microbiological Examination of Space Hardware" (NHB 5340.1). This applies to microbial particle counting and particle concentrating devices which have been calibrated to provide a total or specific number of viable organisms present per unit volume of air.

(d) For quantitation of viable airborne particulates accumulating on surfaces, sterilized fallout collection surfaces shall be used as described in NHB 5340.1. The period of collection shall be based upon the extent of the operations being performed for the product under control.

(e) Other monitoring methods and equipment may be used only if demonstrated to be of accuracy and repeatability equal to the methods listed in paragraphs 5.2.1a, 5.2.1b, 5.2.1c, or 5.2.1d.

5.2.2 MONITORING TECHNIQUES. Monitoring techniques and routines shall be established to demonstrate the reliability of the system to conform to the air cleanliness class as required by the specification for the products involved. Manual microscopic methods are adequate for monitoring non-viable particle concentrations in air in the class

10,000 to 100,000 range. When measuring non-viable particles in air in facilities below the 10,000 class, so few 5.0 micron and larger particles will be present that the manual method may not pick up enough of these size non-viable particles to produce a statistically valid determination; therefore, non-viable particulate air monitoring in the range below class 10,000 shall be done with light scattering equipment.

6. CHANGES

When a NASA program director considers that this standard does not meet the essential needs of a program, requests for alteration of the standard, supported by acceptable justification, shall be made in writing and submitted in triplicate to the National Aeronautics and Space Administration, Office of Space Science and Applications, Director of Bioscience Programs, Washington, D.C. 20546. The Director, Bioscience Programs, shall determine the appropriate action to be taken and shall notify the initiator.

7. CONFLICT WITH REFERENCED DOCUMENTS

Where the requirements of this standard conflict with any document referenced herein, the nature of the conflict shall be described in writing by the person responsible for the discovery of the conflict and shall be submitted in triplicate to the National Aeronautics and Space Administration, Office of Space Science and Applications, Director, Bioscience Programs, Washington, D.C. 20546. Until such time as the apparent conflict may be resolved by the Director, Bioscience Programs, the requirements of this standard shall apply.

APPENDIX A

NONMANDATORY SUPPLEMENTAL GUIDANCE INFORMATION

The purpose of this Appendix is to provide guidance for the preparation of documents relating to the acquisition, operation, and maintenance of bioclean rooms and bioclean work stations. Several approaches to the design and operation of such facilities are presently utilized, each of which is discussed in this document.

One approach, the non-laminar flow room design, makes use of highly filtered and conditioned air brought into the area through individual diffusers located in or near the ceiling, and exhausted through return ducts located in the floor, or near the floor and around the periphery of the room. In this facility, particulate and microbial contamination is limited by controlling personnel, their garments, operations, and materials inside the room. Personnel are required to wear low particle shedding garments, gloves, shoe covers, and have their expired air filtered through a mask. Strict control over entrance, egress, and cleaning of personnel, their garments, and materials is required. Removal of accumulated contamination is through adequate maintenance and custodial services.

Another approach, based on the laminar airflow principle, utilizes highly filtered and conditioned air brought into the room towards the work area through a filter bank comprising an entire wall or ceiling of the room and exhausted through a similar entire surface facing the air inlet filter bank. The air is moved through the room at a reasonably uniform velocity in an unidirectional or "laminar" flow pattern, thus making only a single pass through any given area of the room. This air flow removes from the room any released contamination brought into the room on personnel and equipment or from operations within the room. This prevents the diffusion of contamination which may be generated in localized areas of the room to other areas and critical work is protected by performing the required operations in the undisturbed flow of clean air from the incoming air surface. Personnel restrictions, equipment cleanup, and operational limitations are minimized by conducting such operations downstream of the influent filter wall and the product being controlled.

A third approach, incorporating the exclusion principle, provides for control of personnel contact with the operations through the use of microbiological and particulate barriers and remote handling of the materials. Equipment cleanup and operational requirements are stringent but personnel restrictions are relaxed.

These varied approaches utilize different principles for airborne particle control and each requires a different procedure for implementation.

10. REFERENCED DOCUMENTS

The following documents provide informational guidance to the extent referenced:

10.1 GOVERNMENTAL

TID 7023--High Efficiency Particulate Air Filter Units (HEPA)[1]

MIL-F-51068A--Filter, Particulate, High-Efficiency, Fire Resistant[2]

BWP-30-S Design Criteria for Biological Facilities and Processes, Biological Safety Cabinets Vols. I and II[3]

Public Health Service Publication No. 953, Air Filtration of Microbial Particles[4]

Public Health Monograph No. 60, Sampling Microbiological Aerosols[4]

Federal Standard No. 209a Clean Room and Work Station Requirements, Controlled Environment[5]

10.2 NONGOVERNMENTAL

AMERICAN STANDARDS ASSOCIATION:

ASA Z9.2--The Design and Operation of Local Exhaust Systems

(Requests for copies should be submitted to the American Standards Association, Inc., 10 East 40th Street, N.Y., N.Y. 10016.)

AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS:

Industrial Ventilation Manual

(Requests for copies should be submitted to the American Conference of Governmental Industrial Hygienists, 1014 Broadway, Cincinnati, Ohio 45202.)

AMERICAN SOCIETY OF HEATING, REFRIGERATION, AND AIR CONDITIONING ENGINEERS

ASHRACE Guide

(Requests for copies should be submitted to the American Society of Heating, Refrigeration, and Air Conditioning Engineers, United Engineering Center, 345 E 47th, N.Y., N.Y. 10017.)

SANDIA CORPORATION:

SC-R-64-145-A--Basic Design requirements for laminar airflow dust control devices

SC-TM-64-637--Standard tests for laminar flow devices

(Requests for copies should be submitted to the Sandia Corporation, P.O. Box 5800, Albuquerque, New Mexico 87115.)

[1] Requests for copies should be submitted to U.S. Atomic Energy Commission, Division of Technical Information Extension, P.O. Box 62, Oak Ridge, Tenn. 37830.

[2] Copies of Military Specifications and Standards required by contractors in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.

[3] Requests for copies should be submitted to U.S. Army Edgewood Arsenal, Engineering and Industrial Facility, Edgewood Arsenal, Md. 21010.

[4] Requests for copies should be submitted to Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

[5] Orders for this publication are to be placed with General Services Administration, acting as an agent for the Superintendent of Documents. Single copies of this standard are available without charge at the GSA Business Service Centers in Boston; New York; Atlanta; Chicago; Kansas City, Mo.; Dallas; Denver; San Francisco; Los Angeles; and Seattle, Washington. Additional copies may be purchased for 15 cents each from the General Services Administration, Specifications Activity, Printed Materials Supply Division, Building 197, Naval Weapons Plant, Washington, D.C. 20407.

AMERICAN ASSOCIATION FOR CONTAMINATION CONTROL:

Microbiological barrier equipment and techniques - A State of the Art Report

(Requests for copies should be submitted to the American Association for Contamination Control, 6 Beacon Street, Boston, Massachusetts 02108.)

20. GLOSSARY

20.1 NON-LAMINAR FLOW BIOCLEAN ROOM. A room characterized by no requirement for uniformity of airflow patterns and air velocities.

20.2 NON-LAMINAR FLOW BIOCLEAN WORK STATION. A work station characterized by no requirement for uniformity of airflow patterns and air velocities; but having specific requirements for control of viable particulates. This includes work stations which have constricted air exhaust or ports.

20.3 LAMINAR AIRFLOW. Airflow in which the entire body of air within a confined area moves with uniform velocity along parallel flow lines.

20.4 LAMINAR FLOW BIOCLEAN ROOMS. A room in which the laminar airflow characteristics predominate throughout the entire air space, with a minimum turbulence, and having specific requirements for the control of viable particulates.

20.5 LAMINAR FLOW BIOCLEAN WORK STATION. A work station in which the laminar airflow characteristics predominate throughout the entire air space, with a minimum turbulence, and having specific requirements for the control of viable particulates.

20.6 HIGH EFFICIENCY PARTICULATE AIR FILTER (HEPA). MIL-F-51068A specifies filters with minimum efficiency of 99.97% determined by the homogeneous Dioctyl Phthalate (DOP) method at air flows of 100% and 20% of the rated flow capacity of the filter. It is referred to as the "HEPA" filter.

20.7 FILTER AIR. The air which issues directly from the "HEPA" filter.

20.8 FIRST WORK LOCATION. The work location first in the path of the filter air.

20.9 DYNAMIC AIR SAMPLING. The sampling of the air in the air space to obtain the number of airborne particulates and define those particulates carrying viable microorganisms.

21.0 FALLOUT SAMPLING. The horizontal placement of sterilized strips in the air space for collection of deposited particulates which may have viable microorganisms and which have been airborne prior to deposition on the collection surface.

21.1 MICROBIAL BARRIER SYSTEM. The protection system used to prevent microbial migration and contamination of a product with microorganisms.

21.2 MICROORGANISMS. Microscopic plants or animals in seven principal groups called protozoa, true fungi, mold-like

higher bacteria, true bacteria, spirochetes, rickettsiae, and filtrable viruses.

21.3 AEROSOL. A suspension of ultramicroscopic solid or liquid particles in air or gas.

21.4 DUST. Any powdered matter fine enough to be easily suspended in air or gas.

30. ENVIRONMENTAL CONDITIONS

30.1 AIRBORNE PARTICLE COUNTING. Airborne particle concentrations, viable and non-viable, should be measured at representative locations in the bioclean room or work station. It is necessary to recognize that the differences between non-laminar, laminar airflow, and microbial barrier systems lead to different measuring techniques. For example, any contamination generated in non-laminar flow rooms or work stations tends to be diffused over the entire work area generally, thus airborne particle counts will be fairly uniform through the whole work area. Air samples therefore should be taken at work height level and in the general work activity areas. (Fig. 6)

In laminar flow devices, however, any airborne contamination released into the work area will follow the air stream path toward the exit, therefore, contamination levels in these devices will vary to a marked degree from air cleanliness class 100 to the specific contamination level downstream of the dirtiest operation. Thus, in a laminar flow facility the sample of air should be taken from the air as it approaches the work activity area of interest. Particles count should be taken at work height level and in the general work activity areas.

30.2 RECOMMENDED TEMPERATURE RANGES. Temperatures in the bioclean room should be maintained around a mean temperature of 72°F (22.2°C) for personnel comfort with the exception of those laboratories or work areas for which other temperatures may be necessary for control of stability of items being fabricated or tested or for microorganisms control in which case the mean temperature should be otherwise specified. Choice of temperature may be based on the desired die-away of vegetative microorganisms which, when humidity is held constant, is directly proportional to temperature. The temperature variation at the control point may range from ±0.25°F (±0.14°C) in the most critical operations to as much as ±5.0°F (±2.8°C).

30.3 RELATIVE HUMIDITY RANGES. Relative humidity should be controlled in the bioclean room area. Choice of range should be based primarily upon the product bioclean requirements. Three general problem areas should be recognized:

(a) Rusting of ferrous parts can occur and become a serious problem at relative humidities above 50%.

(b) Electrostatic charges on dielectric and other materials or parts can cause

problems due to particle attraction at low relative humidities.

(c) Microorganism growth and migration can be enhanced at high or low relative humidities, and die-away is most rapid at mid-range.

30.4 MAKE-UP AIR. Make-up air volume supplied to the bioclean room area should meet American Society for Heating, Refrigeration, and Air Conditioning Engineers Guide, or local building code requirements if more stringent. In rooms utilizing a relatively low volume of recirculated air, make-up air should normally be specified as a percentage of the incoming air into the room, e.g., 20% fresh air make-up. In rooms utilizing a high volume of recirculated air, make-up air should normally be specified as a given volume per minute, e.g., 30 cubic feet per minute per person occupancy. When vented hoods are used for vapor control, make-up air volume should be greater than that of the exhausted air in order to maintain a positive pressure in the room. Since a major part of the air conditioning (i.e., heating and cooling) load of a bioclean room may come from the necessity to bring the condition of the make-up air to that of the clean room, consideration should be given to the use of air-to-air rotary heat exchangers or run-around systems in the interest of economy. This is particularly true where large volumes of air must be exhausted to control concentrations of hazardous materials.

When an induction type fumehood employing a separate unfiltered fresh air supply is within any bioclean room area, care should be taken to preclude leakage of the unfiltered fresh air supply into the bioclean room air space.

30.5 PRESSURE. The minimum positive total pressure, static and velocity head, differential between the clean room and any adjacent area of less clean requirements should be 0.05 inches of water, with all entry ways closed. When the entry ways are open, the blower capacity should be adequate to maintain an outward flow of air. This is to minimize migration of contamination into the clean air space. An air pressure safety device should be provided which will prevent pressure buildup above the designed limits for the structure.

40. DESIGN INFORMATION

40.1 NON-LAMINAR FLOW BIOCLEAN ROOM

40.1.1 Bioclean room shell. Bioclean room shell, floor, walls, and ceiling should be designed and constructed in a manner required to eliminate air leaks into or from the bioclean room. The walls and ceiling material should be low particle shedding, easy to clean, and capable of withstanding decontamination procedures. The floor covering should be low particle shedding, tightly joined to prevent particle accumulation in seams and sufficiently durable to withstand wear imposed by traffic, decontamination procedures, and bioclean room operations.

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40.1.2 Entry ways. Entry ways, doors, and pass-throughs should be of correct size to permit personnel and required equipment access to the clean room. These entry ways should be the air lock type with interacting locks on all doors, should provide air seals sufficient to allow pressurization of the bioclean room, and should be ventilated to provide flushing of air space inside the lock.

40.1.3 Anterooms. Anterooms should be provided for bioclean room personnel clothing change area, clothing storage, wash up facilities, air showers, and other equipment for personnel bioclean room entry requirements. Anterooms may also be provided, as needed, to house parts cleaning and other room support equipment.

40.1.4 Air supply and filtration equipment. Air supply and filtration equipment should be provided to filter air entering the bioclean room, recirculated as well as fresh air. A three minute room air change is usually considered to be minimum for 8 to 12 foot (2.438 to 3.658 meters) ceiling height rooms. Equipment should be provided to supply fresh, or make-up air, as required.

Consideration should be given for ease of access to the filter bank for changing and testing of the filters, and the ducts leading to and from the filters.

40.1.5 Air conditioning equipment. Air conditioning equipment for cooling, heating, humidification, and dehumidification of the bioclean room air should be provided as required.

40.1.6 Bioclean room furnishings. Bioclean room furniture and equipment should meet bioclean room operational needs, should be constructed of low particle shedding materials, and be devoid of coatings which are subject to erosion and particle production from use.

40.1.7 Bioclean room lighting equipment. Bioclean room lighting equipment should be provided to meet work requirements within the bioclean room. Shadowless, uniform lighting at intensity levels of 100 to 150 footcandles (1076 to 1614 lux) at work station is satisfactory for most bioclean rooms. Light fixtures should be flush mounted, and sealed to prevent air leaks.

40.1.8 Fire protection. Bioclean room fire protection should be consistent with product and local requirements.

40.2 LAMINAR FLOW BIOCLEAN ROOM

40.2.1 Bioclean room shell. For economy of operation and product protection, laminar air flow bioclean rooms should have floor, walls, and ceiling assembled in such a manner so as to inhibit the leaking of any air into or from the room. The materials for walls and ceiling

should be low shedding, easy to clean, and capable of withstanding decontamination procedures. The floor covering, on other than vertical laminar air flow facilities or wall-to-floor air flow facilities, should be low particle shedding and sufficiently durable to withstand wear imposed by traffic, decontamination procedures, and bioclean room operations.

40.2.2 Entry ways. Entry ways, doors, and pass-throughs should be of sufficient size to permit entrance and exit of personnel and required equipment. These openings should provide an air seal when closed to allow pressurization of the area. The use of air lock and air shower type facilities should be based upon products and personnel considerations.

40.2.3 Anterooms. Anterooms should be provided for storage of personnel clothing, lunches, personal property, washing facilities, and cleaning equipment.

40.2.4 Air conditioning equipment. Air conditioning equipment for cooling, heating, humidification, and dehumidification of the bioclean room air supply should be provided as required.

40.2.5 Bioclean room furnishings. The furniture and equipment should meet bioclean room operational needs, should be constructed of low particle shedding materials, and be devoid of coatings which are subject to erosion and particle production from use.

40.2.6 Bioclean room lighting equipment. Shadowless, uniform lighting at intensity levels satisfactory at normal working levels should be designated as required. Ceiling lighting fixtures in horizontal laminar flow rooms may be suspended into the clean room to eliminate the necessity for sealing, but such fixtures should be as streamlined as possible. If the fixture clearance above the working surface is exceptionally close, it would be proper to employ recessed and sealed fixtures.

40.2.7 Laminar airflow. Several configurations are feasible with laminar airflow, some of which are:

40.2.7.1 Wall-to-floor airflow. As displayed in Figure 1, this design is adaptable to a wide choice of sizes, inasmuch as the length is limited only by the space available.

40.2.7.2 Ceiling-to-floor airflow. This vertical airflow design has the capability of providing the highest degree of bioclean atmosphere in a dynamic air system because any contamination generated by a specific operation is immediately carried down and out of the room, thus providing an opportunity to perform many functions which otherwise would be accomplished elsewhere, transported through a cleaning operation, and then brought to the bioclean room (Fig. 2)

40.2.7.3 Wall-to-wall airflow. Horizontal rooms, as shown in Figure 3, represent a minimal investment with a potential for a high degree of contamination control.

40.2.7.4 Room-within-a-room airflow facilities. Employing a filter bank (normally a combination of prefabricated modules) and inexpensive side walls and ceiling with an open exhaust opposite to the filter bank, the room-within-a-room resembles a tunnel of any height, width, and length which may be fabricated inside an existing conventional facility. Figure 4 depicts this type of installation which is the least costly of any type of room, and can be disassembled and moved with a minimum of time and effort. Its effectiveness is comparable to the wall-to-wall airflow room.

Acceptable temporary bioclean room areas have been constructed using prefabricated modules (which are complete units containing both supply fan and "HEPA" filters) and flexible plastic walls and ceilings with a completely open end. The bioclean room area in this case resembles a plastic tube, and the ceiling and side walls are supported by a simple exterior pipe or angle iron framework.

40.2.7.5 Mobile curtained downflow facilities. These facilities may be constructed in a wide choice of sizes and heights, and can provide a high degree of contamination control for large and difficult-to-move structures on which assembly is to be accomplished under exacting controlled conditions. (See Figure 5.)

40.2.8 Incoming air filter bank. The incoming air filter bank of laminar flow rooms should cover either one entire wall or the entire ceiling, except when built-in benches are included at the incoming air end of the room (see Figures 1, 3, and 4), the wall filter bank may be modified to cover only the area extending from the bench working surface to the ceiling. In every instance a laminar airflow room should be class 100 in the zone immediately adjacent to the incoming air entry area. The face of the filters should be protected from damage.

40.2.9 Final filters. All final filters should be of the "HEPA" type, or better. For laminar flow installations, "HEPA" filters in which pinhole and other localized leaks have been sealed off should be specified. DOP smoke penetration test ratings should include penetration through filter gaskets, if present. (See par. 20.6.)

40.2.10 Prefilters. Prefilters should be used on all fresh air make-up supply, and on recirculated air to prolong the life of HEPA filters. Efficiency of the prefilters should be tailored to the anticipated contamination load.

40.2.11 Air exit. The air exit from these rooms should consist of an entire wall or grated floor surface. The use of prefiltration located back of the exit wall grills, or beneath the grated or perforated floor, will provide pressure drop across the exit area to help assure a uniform room airflow. Manually operated dampers in the air exhaust area of the bioclean rooms may be required to maintain the laminar airflow characteristics.

40.2.12 Airflow velocity. Airflow velocity through the cross section of the room normally is maintained at 90 feet (27.45 meters) per minute with a uniformity with ± 20 feet (± 6.10 meters) per minute throughout the undisturbed room area.

40.2.13 Airflow patterns. Airflow patterns should be uniform and with a minimum of turbulence throughout the undisturbed portions of the clean room.

40.3 LAMINAR FLOW BIOCLEAN WORK STATION. Bioclean work stations defined by this document as the laminar flow type should meet the following: (see Figure 7).

40.3.1 Bioclean work station shell. The materials for the sides and work surface for laminar airflow bioclean work stations should be low shedding and the finish should be easily cleanable. The work surface should be able to withstand wear imposed by operations within the work station.

40.3.2 Airflow containment. Side panels, and work surfaces should be such that they will provide cross section area equal to the filter face. Under normal circumstances these containment surfaces should be perpendicular to the filter face.

40.3.3 Final filters. All final filters should be of the "HEPA" type, should make-up the rear or top surface of the enclosure, should cover the entire area of that surface, and the effective filter area should be flush with the containment surfaces. The face of the filters should be protected from damage without obstructing the airflow pattern.

40.3.4 Prefilters. Prefilters should be used to prolong the life of the "HEPA" filters. The efficiency of the prefilters should be tailored to the anticipated contamination load and the desired life of the "HEPA" filters.

40.3.5 Air exit. The air exit of the enclosure should be equal in area to the exposed surface of the final "HEPA" filters.

40.3.6 Airflow velocity. Airflow velocity from the air exit of an unobstructed work station should be maintained at 90 feet (27.45 meters) per minute (f.p.m.) average minimum with a uniformity within ± 20 (± 6.10 meters) f.p.m. across the entire area of the exit, to within 1 inch (2.54 centimeters) of the

containment surfaces. Outside air should not be aspirated into the work area.

40.3.7 Airflow patterns. Airflow patterns should be uniform with a minimum turbulent pattern in the unobstructed areas of the enclosure.

40.4 MICROBIAL BARRIER SYSTEM. Microbial barriers as defined by this document should meet the following: (see Figures 9, 10, and 11).

40.4.1 Containment shell. The containment shell may be heavy-walled stainless steel, thin-walled stainless steel, flexible plastic or rigid plastic depending on the manipulations to be performed and sizes of items to be processed. BWP-30-S provides specifications and drawings for nine types of biological safety cabinets used as mechanical barriers between product and fabrication. The shell should be designed so that the contents can be observed, manipulated, and materials introduced and removed without destroying the integrity of the mechanical barrier. The materials used should be compatible with the sterilization and decontamination agents used for the interior of the barrier and be free of cracks or joints which would resist decontamination. The shell should be designed to contain 3 inches (7.62 cm) of water pressure maximum.

40.4.2 Openings. Doors, and pass throughs should be of sufficient size to permit introduction and removal of required equipment and items before and after assembly. A double barrier system should be employed for all openings to permit sterilization and decontamination of the materials and equipment prior to their being introduced into the working chamber. The closures for the openings when in place should be capable of maintaining 3 inches (7.62 cm) of water pressure without detectable leakage.

40.4.3 Ventilation. Internal ventilation or circulation patterns for gas-tight barriers should be determined by the nature of the operation. Fabrication procedures may require ventilation with inert gases or precise control of temperature and humidity within the barrier.

40.4.4 Manipulation ports. Gas-tight removable panels containing an arrangement of ports for attachment of arm length gloves, manipulator arms, or tunnel suits for manipulation of items within the gas-tight barrier should be provided. These panels should be so located that the entire enclosed working space and pass throughs may be reached by the manipulator. The ports, panels, gloves, tunnel suits, and manipulator system should be capable of maintaining 3 inches (7.62 cm) of water pressure without detectable leakage.

40.4.5 Viewing panels. Visual viewing panels should be provided to permit the operator to clearly observe all

manipulations within the gas-tight enclosure, pass throughs, and decontamination or sterilization chambers. The panels should be capable of maintaining 3 inches (7.62 cm) of water pressure without detectable leakage and be of the double wall type to provide safety for the operator against accidental breakage. The materials should be compatible with the decontamination and sterilization procedure to be used and with the intended operations to be performed within the chamber.

40.4.6 Utility services. Services such as electricity, gas, vacuum, air, water, and drains should be provided as required for the manipulations to be performed. Safety and contamination control procedures for each service should be specified for the intended operations to be performed within the chamber. A differential pressure relief system should be provided to prevent structural damage from excessive pressure build up.

40.4.7 Lighting. Shadowless, uniform lighting at intensity levels satisfactory at normal working levels should be provided as required. Lighting fixtures should be recessed externally accessible to the gas-tight chamber, and sealed to maintain 3 inches (7.62 cm) of water pressure without leakage.

50. TESTS

50.1 LAMINAR FLOW ROOM

50.1.1 Filtration tests. An in-place filter test should be made to determine that the "HEPA" filter bank contains no pin hole leaks in (1) the filter media itself, (2) the bond between the filter media and the interior of the filter frame, and (3) the filter frame gasket and the filter bank supporting frames.

Leak tests should be made by introducing a high concentration of smoke or fog[1] into the plenum upstream of the "HEPA" filters (concentration should be of the order of 10^4 above the minimum sensitivity of the photometer used as the detector; this normally will be in the order of 80 to 100 micrograms per liter). The entire downstream surface of the "HEPA" filter installation should then be scanned by moving an aerosol photometer probe at approximately 0.5 inch (1.27 cm) per second at a sampling rate of one (1) cubic foot (0.02832 cubic meter) per minute held 1 to 2 inches (2.54 to 5.08 cm) from the filter media and frame. The probe should be sized to provide approximately isokinetic sampling and should be held 1 to 2 inches (2.54 to 5.08 cm) from the filter media and frame. Thus, for measuring laminar flow equipment having air velocities of from 70 to 110 feet per minute, the probe should be sized from 1 to 1.5 inches squared. An aerosol

[1] For example, cold generated DOP Fog. Ref: NRL 5929 "Studies of Portable Air-Operated Aerosol Generators," Echols and Young, Clearing House for Federal, Scientific, and Technical Information, Springfield, Virginia 22151.

photometer reading equivalent to 0.01 percent of the upstream smoke concentration is considered a significant leak and should be sealed off.

50.1.2 Airflow velocity. Airflow velocity should be measured through the cross section of the room and should conform to paragraph 40.2.12.

50.1.3 Viable particulate test. Effectiveness of microbiological filtration should be determined as described in NASA NHB5340.1, Public Health Monograph No. 60, and Public Health Service Publication No. 953.

50.2 NON-LAMINAR FLOW ROOM

50.2.1 Filtration tests. Same as per laminar flow rooms (par. 50.1.1) except that scanning should be done at the downstream surface of the "HEPA" filter, if it is readily accessible.

50.2.2 Duct tests. Aspiration of contamination from leaks in the ducts (between the filters and the room inlet) should be considered and particulate tests made at the point of air inlet.

50.2.3 Viable particulate tests. Same as per laminar flow rooms, (paragraph 50.1.3).

50.3 LAMINAR FLOW BIOCLEAN WORK STATION

50.3.1 Filtration tests. All tests for filtration effectiveness for laminar flow bioclean work stations should be (Per laminar flow rooms, 50.1.1) by introducing smoke into the intake ducts.

50.3.2 Airflow velocity tests. Airflow velocity out of the air exit of an unobstructed bioclean work station should conform to paragraph 40.2.12 and be measured through the cross section of the unobstructed open face of the air exit.

50.3.3 Viable particulate tests. Effectiveness of control of microbial filtration should be determined as per laminar flow rooms (paragraph 50.1.3).

50.4 NON-LAMINAR FLOW BIOCLEAN WORK STATION

50.4.1 Filtration tests. Check for leaks (per laminar flow rooms, 50.1.1) except that scanning is required to be done at the downstream surface of the "HEPA" filter, if it is readily accessible.

50.4.2 Viable particulate tests. Effectiveness of microbial control should be determined as per laminar flow rooms (par. 50.1.3).

50.5 MICROBIAL BARRIER SYSTEM

50.5.1 Tightness tests. A barrier system should be evaluated for microbial tightness by determining its gas-tightness or leakage rate. The ability to contain gas molecules for specified time periods is evidence that the system will prevent leakage of contamination through the barrier. For small chambers, under 1,000 cubic feet

in volume (28.32 cubic meters), the halogen leak detector, having a maximum sensitivity of 1×10^{-9} cc of halogen gas per second, is the preferred instrumented method for leak detection. Freon-12 gas should be introduced into the chamber in an amount of 1 ounce per 30 cubic feet (29.6 ml per 0.85 cubic meters) of enclosure and the pressure maintained at 5 inches (12.7 cm) of water equivalent on the gauge. The room in which the tests are performed must be halogen free and no smoking should be permitted. The nozzle of the probe should be held at the surface of the unit being tested in a manner not to jar the instrument and moved over the surface at approximately 0.5 inch (1.27 cm) per second. Any indication on the detector should be cause for sealing off the leak.

For large chambers and rooms, the leak test should be designed to minimize the risk of structural damage from excessive pressure. The chamber should be completely closed and air added until the pressure in the room is 1.0 inch water guage. At this point the air is shut off and the pressure is noted in 10-minute intervals for a period of 1 hour. A room is considered to be adequately sealed if during one hour the pressure drop is from 1.0 to 0 inch of water gauge (0.020 to 0.025 air changes per day equivalent).

50.5.2 Viable particulate tests. Verification of sterility of microbial barrier systems should be done under a dynamic condition of activity within the containment system in accordance with procedures for laminar flow rooms (par. 50.1.3). Any detectable contamination should be carefully evaluated to determine steps required to isolate the cause and institute correction.

60. MONITORING

60.1 NON-LAMINAR FLOW BIOCLEAN ROOM

60.1.1 Airborne particulates. Viable and non-viable particle counts should be taken at representative locations at specified intervals to reflect maximum and minimum periods of activity.

60.1.2 Particulate disposition. Settling strips should be located at representative locations in sufficient quantity to provide for determination of microbial profile of the room with respect to time.

60.2 LAMINAR FLOW BIOCLEAN ROOM

60.2.1 Airborne particulates. Monitoring of the first air pass in laminar flow rooms and work stations can be accomplished using a facility check out procedure. By a deductive process it can be determined that the contamination level of the facility is acceptable if the filters pass the leak test, airflow is uniform, and the air velocity and viable particulate tests are passed as described in paragraphs 50.1

and 50.3. In most situations this type of facility check will be more meaningful than an attempt to make an actual airborne particle count, due to the extremely low particle concentrations expected, plus the difficulty of taking a representative sample in a laminar flow air stream.

60.2.2 Particulate deposition. In order to provide a microbial profile of the numbers of viable particulates accumulating on horizontal surfaces in the room, settling strips should be placed downstream from the filter face and at the air exit for horizontal cross flow rooms and above and below the working elevation for vertical downflow rooms. A portion of these strips should be removed and analyzed at intervals consistent with work activity in the room.

60.3 NON-LAMINAR FLOW BIOCLEAN WORK STATION

60.3.1 Airborne particulates. All work stations should be monitored at specified intervals dependent upon the work activity.

60.3.2 Particulate deposition. All work stations should be monitored for surface deposition of viable airborne particulates through use of settling strips which are analyzed at specified intervals dependent upon the work activity.

60.4 LAMINAR FLOW BIOCLEAN WORK STATION

60.4.1 Airborne particulates. All new work stations, relocated work stations, and work stations in which "HEPA" filters have been repaired or replaced with new "HEPA" filters should be monitored (per laminar flow work stations, 50.3) after being placed in operation and thereafter as stipulated in the specifications.

60.4.2 Particulate deposition. Monitoring of viable particulates accumulating on horizontal working surfaces should be accomplished by placing settling strips within the working area for analysis at specified intervals dependent upon the work activity.

60.5 CHANGING OF "HEPA" FILTERS

60.5.1 Airflow change. When the airflow drops below the minimum rate, and new prefilters do not increase the flow, "HEPA" filters should be replaced.

60.5.2 Filter backpressure. When the static pressure drop across the filters exceeds the static capability of the blowers, the "HEPA" filters should be replaced.

60.5.3 Uncorrectable leakage. When the "HEPA" filters develop uncorrectable leakage leading to consistently abnormal particle counts within the area, they should be replaced.

60.5.4 Filter monitoring. Whenever "HEPA" filters are changed, a thorough leak check should be made as described in 50.1 and 50.3.

60.6 MICROBIAL BARRIER SYSTEM

60.6.1 Decontamination. Monitoring of effectiveness of decontamination within the barrier system should result from swab, Rodac plate, or strip sampling of surfaces in accordance with procedures outlined in NHB 5340.1. These results should not exceed those specified for the particular bioclean air cleanliness classification.

60.6.2 Sterilization. Monitoring of effectiveness of sterilization within the barrier system should be based upon consideration of the time-temperature-humidity relations of the agent known to produce sterility. Selected samples should be taken of surfaces, using the procedures outlined in NHB5340.1.

60.6.3 Air balance. Internal ventilation patterns for gas-tight barriers should be determined by the nature of the operation. Some procedures may require ventilation with inert gases or accurate control of temperature and humidity within the barrier. The rate of contamination generation within the barrier should be monitored by using procedures outlined in NHB5340.1.

70. OPERATIONAL GUIDES

70.1 GENERAL

70.1.1 Equipment cleaning and decontamination. All equipment should be cleaned and decontaminated before being passed into the bioclean environment by dusting, vacuuming, washing, dunking, or by suitable means, compatible with the equipment involved.

70.1.2 Personnel covering. All personnel should wear lint-free, non-shedding garments in the bioclean area. Head covering which covers the the entire head should be used to avoid part or component contamination by loose bits of hair or loose skin flakes.

70.1.3 Cosmetics. Hand lotions, creams, or soap containing lanolin to tighten skin particles should be used as appropriate. Cosmetics and medication which may produce contamination should not be permitted. In particular, eye make-up, rouge, face powder, and hair spray should not be used and fingernail polish should be removed before entering the bioclean area.

70.1.4 Smoking and eating. Under no conditions should smoking or eating be permitted in the bioclean area.

70.1.5 Parts handling methods. Gloves, tweezers, or other mechanical barriers to prevent contact between skin and hardware should be used while working with or handling sensitive parts to avoid contamination of those parts by loose skin, microbiota, or natural skin oils. Solvent contact with hands should be avoided, as many solvents remove natural skin oils causing excessive "skin peeling" or flaking.

70.1.6 Paper and writing materials. Paper should be limited to the non-shedding type or enclosed in a transparent non-shedding covering when used in the bioclean area. Only ball point pens should be used for writing. Lead pencils and erasers should not be permitted in the bioclean area.

70.1.7 Custodial equipment. All equipment used to maintain the cleanliness of the bioclean area should be stored within the bioclean area in a manner which will prevent accumulation or dispersion of particulates or microbiota on the surfaces and reduce particulate shedding when used. Vacuum hoses, electric cables, and other flexible conductors should be stored on reels or racks off the floor of the bioclean area. Synthetic sponge mops should be hung so that the mop head does not touch the floor. Use of bristle brushes, steel wool, and other particle shedding materials should not be permitted. All such equipment entering the bioclean area should be treated as per paragraph 70.1.1.

70.1.8 Machining and mating exhausts. Exhaust systems for grinding, welding, soldering machining, or other related operations should be installed in accordance with the Industrial Ventilation Manual published by the American Conference of Governmental Industrial Hygienists, and the ASA Standard Z9.2, "The Design and Operation of Local Exhaust Systems."

70.2 PARTS CLEANING AND HANDLING

70.2.1 Cleaning operations. Before being transported into the bioclean area, all parts, instruments, materials, and systems should be cleaned as required to prevent contamination of the room. To prevent direct transfer of contamination, constant surveillance of the established procedures for handling clean parts and assemblies is recommended. Particular attention should be paid to cleaning operations that are performed in the bioclean room. Ultrasonic cleaners, spray rinses, and volatile immersion baths may release liquid droplets containing contaminants into the room air. The design of the cleaning equipment, and its location in the room should be selected to minimize this problem. Where practical, contamination producing operations should be located in adjoining areas, and the work should be passed into the bioclean room without cross contamination after the operation has been performed.

70.2.2 Containers. Transport and storage containers should be made of low particle shedding materials. They should also have as rigorous a cleaning schedule as the parts or equipment. Care should be taken to insure that containers used for transporting cleaned parts do not transfer contamination from surface to surface in the bioclean room.

70.3 NON-LAMINAR FLOW BIOCLEAN ROOM

70.3.1 Traffic control. Strict control over personnel ingress and egress into the bioclean area should be exercised. Access should be limited to only those persons necessary for operations within the area. Shoes should be cleaned, covered, or changed before entering the area.

70.3.2 Custodial services. Maintenance and janitorial operations should be restricted during normal bioclean room operations to avoid airborne particle generation and should consist of a properly supervised, regularly scheduled program. Where energency or routine contamination producing operations are to be performed, normal work should be discontinued, the equipment and parts covered in a protective manner, and the room cleaned.

70.3.3 Particle control operations. Use of compressed air or other high velocity gases for blow off or cleaning operations, except under exhaust hoods capable of carrying residue to exterior of bioclean room, should be avoided. The use of airborne particle controlled hoods or work stations are recommended where feasible. These hoods will provide a high degree of cleanliness at reasonable costs. Usually such hoods are satisfactory for small parts not requiring large tooling fixtures, and in some cases these hoods can be adapted to large tools or to continuous assembly line type operations. (See Figure 8.)

70.4 LAMINAR FLOW BIOCLEAN DEVICES

70.4.1 Bioclean work station. Care should be taken to locate work stations in an area where no opposing air currents could carry dust into the work station. Work station blowers should be started at least 15 minutes prior to use and filtration checks made in accordance with procedures outlined in Section 30. Fixtures, protective filter grille, and work bench surface should be cleaned before use (vacuum and wipe). Obstruction to the airflow should be kept to a minimum in the work station, particularly upstream from the critical work.

70.4.2 Ceiling-to-floor and wall-to-floor bioclean room. The bioclean room blowers should be started at least 15 minutes prior to use of the room and checks should be made for proper filtration of incoming air in accordance with procedures outlined in Section 30.

70.4.3 Cross flow bioclean room (horizontal laminar flow). The bioclean room blowers should be started at least 15 minutes prior to use of the room and checks made for proper operation of filters in accordance with procedures outlined in Section 30. Obstructions to the airflow should be kept to a minimum, particularly upstream from critical work, and arrangement of furnishings within the room should be made to allow as free an

airflow across the room as is possible. Operations should be graded according to required cleanliness levels for critical work. Most critical operations should be nearest the influent filter wall.

70.5 MICROBIAL BARRIER SYSTEM

70.5.1 Decontamination. All steps to be conducted within the assembly chamber should be planned thoroughly so that all necessary tools, solvents, writing materials, and equipment are present in the chamber when decontamination operations start. A suspension system for components awaiting assembly in the chamber should be provided to assure contact between the component surface and the decontaminant. Special fixtures and tools for reaching, transferring, and holding assembled items should be provided within the chamber, should occupy little space, and be easy to decontaminate.

70.5.2 Purging. The assembly chamber atmosphere should be purged with an inert gas after operations involving high temperatures, such as dip soldering to remove metal vapors. A daily purge is also desirable after completion of operations to remove any generated vapors which may produce a residue on the production items during residence in the chamber.

70.5.3 Environmental control. An electronic humidity-indicating system should be used rather than a device which introduces water vapor into the closed atmosphere. A gas circulation system should be provided within the assembly chamber to assure even distribution of humidity and temperature throughout the chamber. A small vacuum cleaner should be included in the inventory of tools for frequent use in maintaining particulate cleanliness of the chamber. Provision should be made to maintain the chamber at a minimum of 0.05 inch equivalent water pressure with a relief system for maximum pressure of 2 inches.

80. GUIDELINES FOR ACHIEVING VARIOUS BIOCLEAN ROOM CLASSES

80.1 GENERAL. There are a number of different approaches that a bioclean room designer or user may take to achieve a particular bioclean room cleanliness classification. Table III illustrates the class that normally may be achieved using the different approaches.

80.2 EXISTING FACILITIES. Existing bioclean facilities may be available and may be used if they achieve the cleanliness classification requirements described in Table III.

80.3 UPGRADING EXISTING FACILITIES. Existing conventional facilities which do not achieve the desired cleanliness classification may be effectively upgraded by replacing existing work benches with laminar flow work stations or by placing filter bank modules

in the room to recirculate large quantities of the room air.

80.4 NEW CONSTRUCTION. New construction may be required if no bioclean facilities exist or are available, upgrading existing facilities is undesirable or more costly than new facilities, or additional bioclean room space is required. In new construction, the laminar airflow principle or microbial barrier system should be considered, for which several options are available (see Table III).

TABLE III. GUIDELINES FOR ACHIEVING BIOCLEAN ROOM CLEANLINESS CLASSES

	Use Existing Facilities	Upgrade Existing Facilities	New Construction				
	Non-laminar and laminar flow rooms, tunnel, downflow units, and microbial barrier systems.	Using laminar flow bioclean work stations, tunnels, downflow units, and microbial barrier systems.	Laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems used in uncontrolled areas.	Laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems used in controlled areas.	Laminar cross flow type rooms.	Laminar flow grating floor type rooms.	Germ-free environmental room.
Class 100 (3.5)	1. All laminar flow grating floor rooms, bioclean work stations, downflow units, and microbial barrier systems. 2. First work locations in cross flow rooms and tunnel units will meet requirements.	1. Area within bioclean work stations. 2. First work locations in tunnel units. 3. Area inside downflow units. 4. Area inside microbial barrier system will meet requirements.	1. Area within bioclean work stations, downflow units, and microbial barrier systems will meet requirements. 2. First work locations in tunnel units will meet requirements.	1. Area within bioclean work stations, downflow units, and microbial barrier systems will meet requirements.	First work locations will meet requirements.	Entire room work area will normally meet requirements.	Entire room work area will meet requirements.
Class 10,000 (350)	1. Some non-laminar flow rooms and bioclean work stations may meet requirements. 2. Most areas in laminar cross flow rooms and tunnel units should meet requirements. 3. All laminar flow grating floor rooms, laminar flow bioclean work stations, downflow units, and microbial barrier systems will meet requirements.	1. Non-laminar flow rooms with laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems may meet requirements. 2. Most areas inside tunnel units should meet requirements. 3. Area inside bioclean work stations, downflow units, and microbial barrier systems will meet requirements.	1. Area inside clean work stations, downflow units, and microbial barrier systems will meet requirements 2. Most areas inside tunnel units should meet requirements.	1. General area may meet requirements depending upon ratio of recirculated filtered air to volume of area. 2. Most areas inside tunnel units should meet requirements.	Most areas in room should meet requirements.	Entire room work will normally meet requirements.	Entire room work area will meet requirements.
Class 100,000 (3500)	1. Most non-laminar flow rooms and bioclean work stations will meet requirements. 2. All laminar flow rooms, bioclean work stations, tunnel, downflow units, and microbial barrier systems will meet requirements.	1. Poor quality non-laminar flow rooms with laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems may meet requirements depending upon ratio of recirculated filtered air to room volume. 2. Area inside bioclean work stations, tunnel, downflow units, and microbial barrier systems will meet requirements.	Area inside bioclean work stations, tunnel downflow units, and microbial barrier systems will meet requirements.	1. General area will normally meet requirements depending upon rate of recirculated filtered air to volume of controlled area. 2. Area inside bioclean work stations, tunnel, downflow units, and microbial barrier systems will meet requirements.	All areas in room will normally meet requirements.	Entire room work area will normally meet requirements.	Entire room work area will meet requirements.

NOTES:
1. Laminar flow work stations include bioclean room benches and bioclean air exhaust hoods, Figures 7 and 8.
2. Tunnel units indicate laminar cross flow facilities, open on one end to exhaust into surrounding area, Figure 4.
3. Downflow units indicate vertical flow curtained modules, Figure 5.
4. Microbial barrier systems indicate absolute containment enclosure, Figure 9.
5. Germ-free environmental room indicates a sterile room in which the operations are performed remotely or with the personnel contained in an externally ventilated barrier suit. Figures 10 and 11.

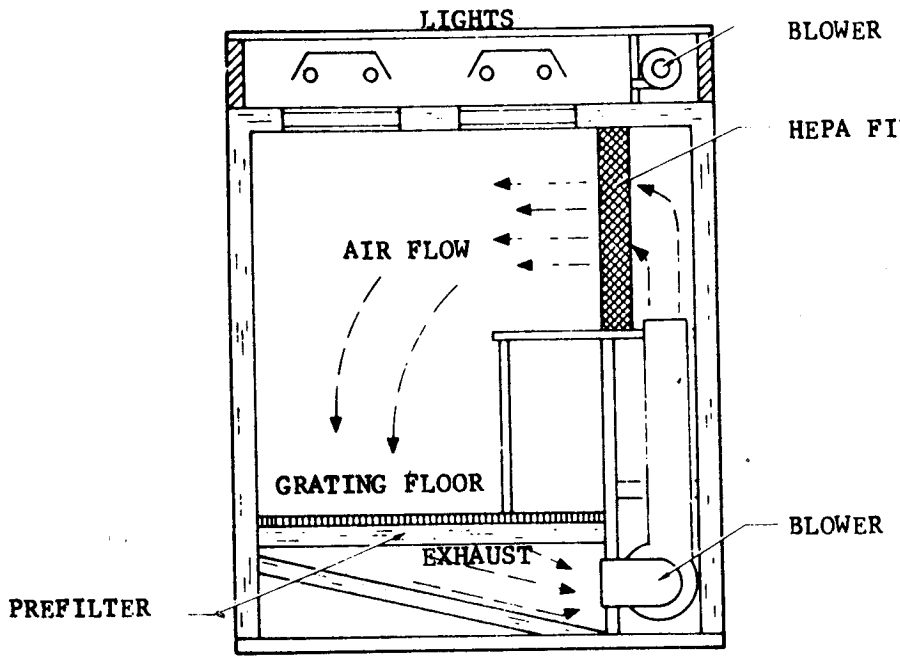


Figure 1.--Wall-to-floor air flow

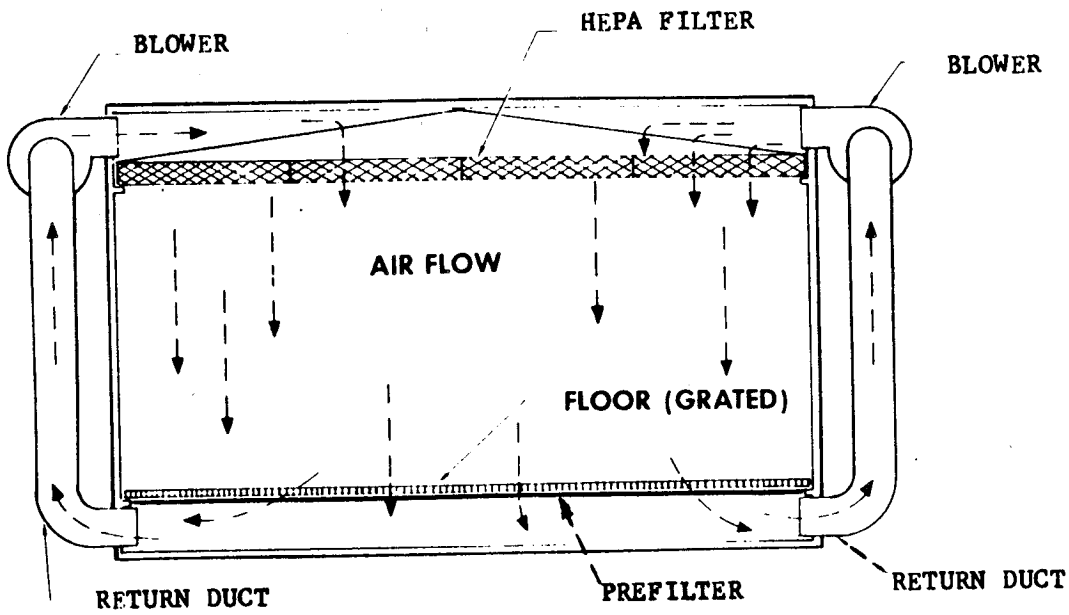


Figure 2.--Ceiling-to-floor air flow

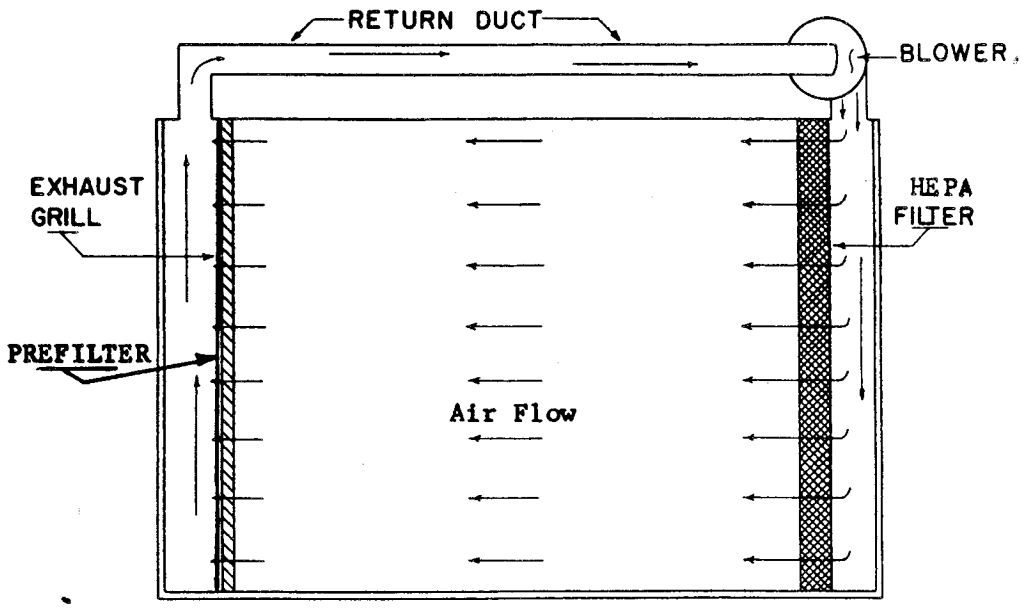


Figure 3.--Wall-to-wall air flow

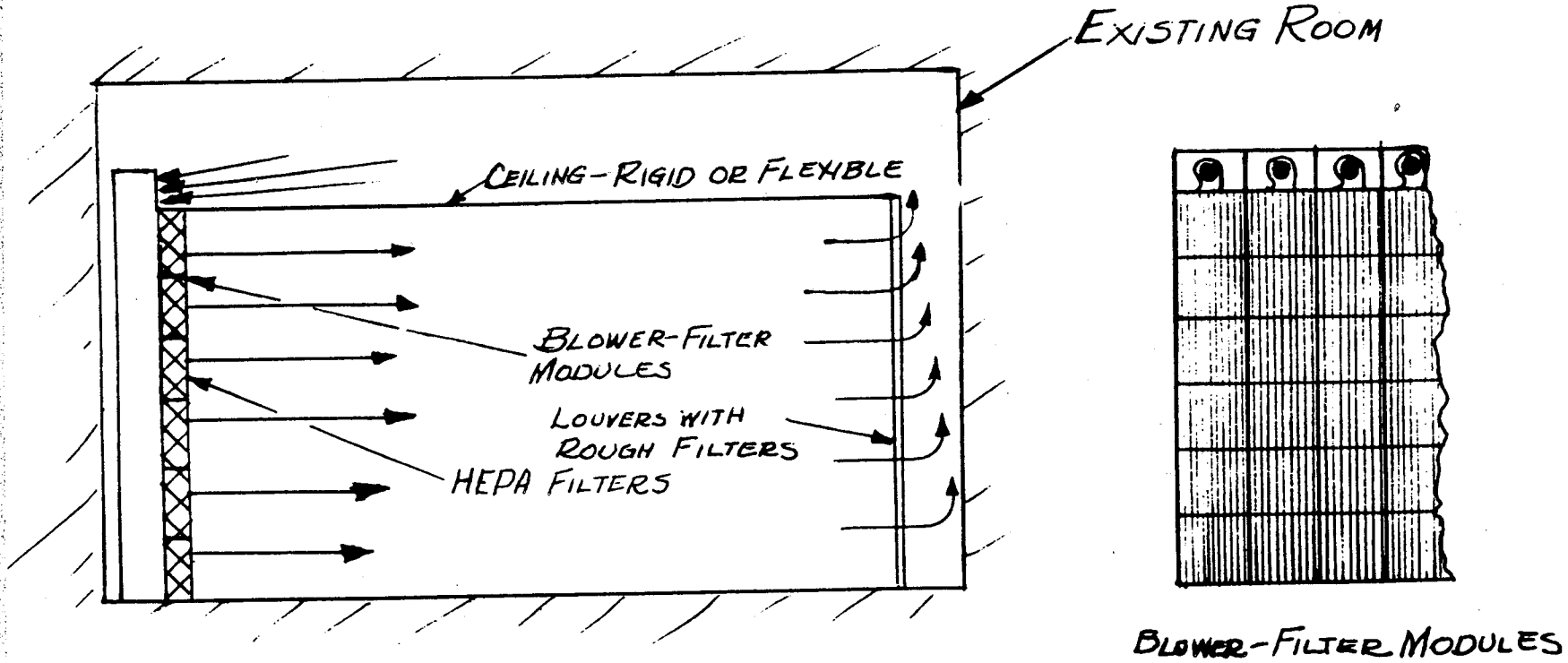


Figure 4.--Mobile or Stationary Wall-to-Wall airflow Room-within-a-Room

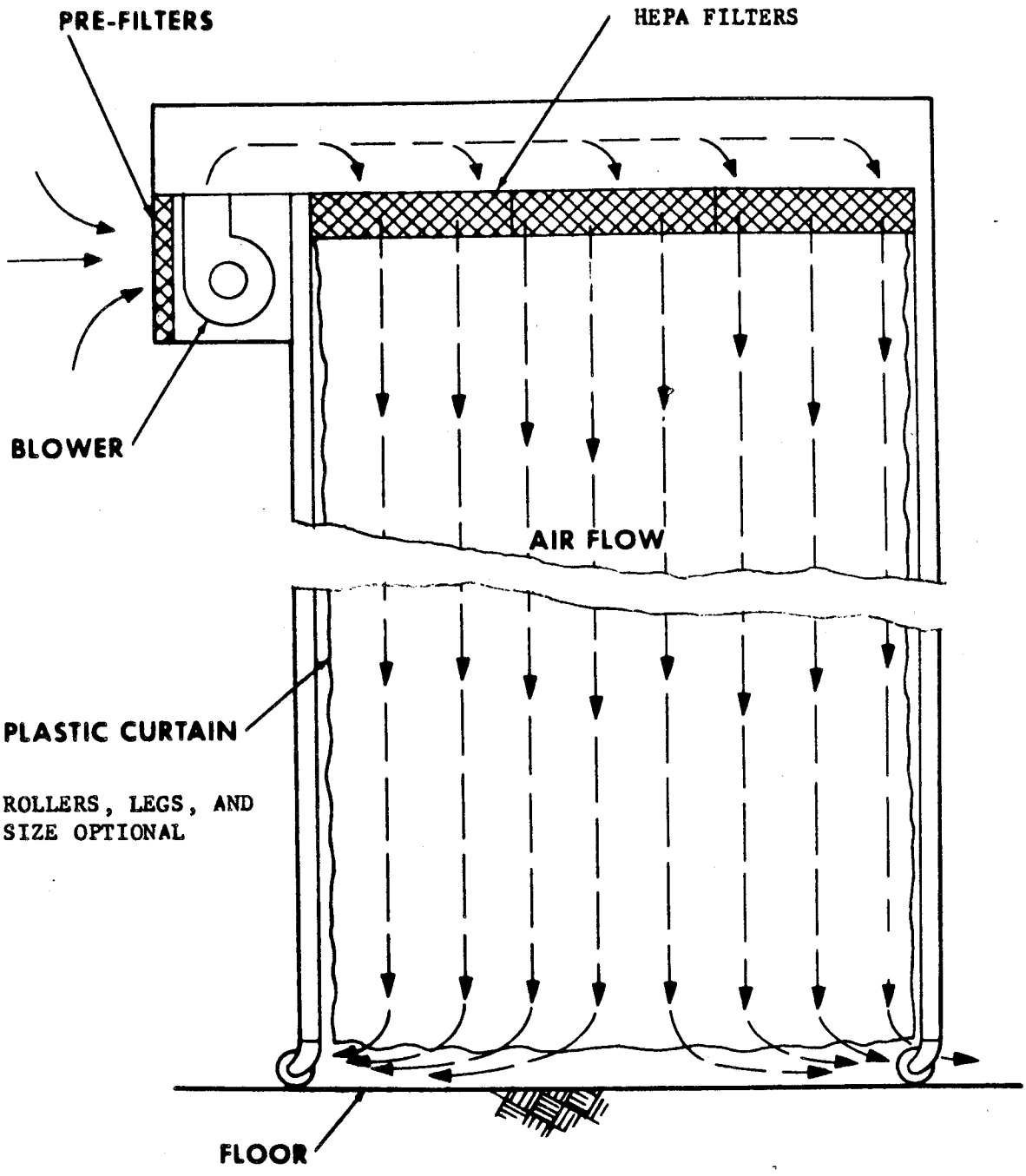
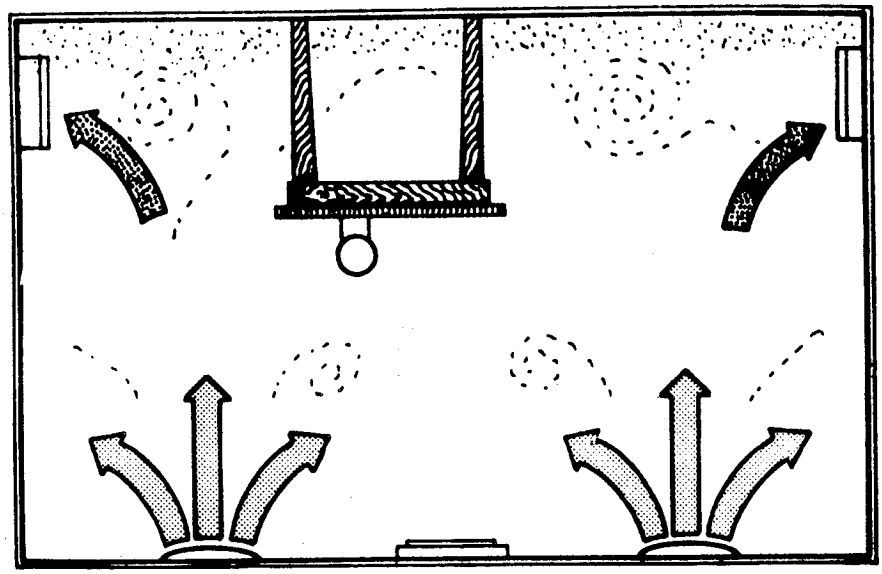


Figure 5.--Mobile curtained down-flow unit



Side Elevation

Figure 6.--Non-laminar air flow room

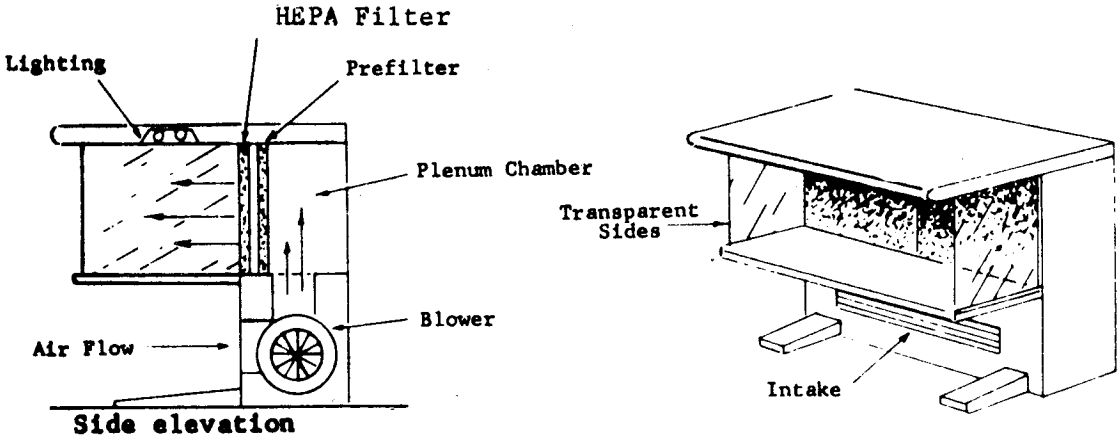


Figure 7.--Laminar flow work station

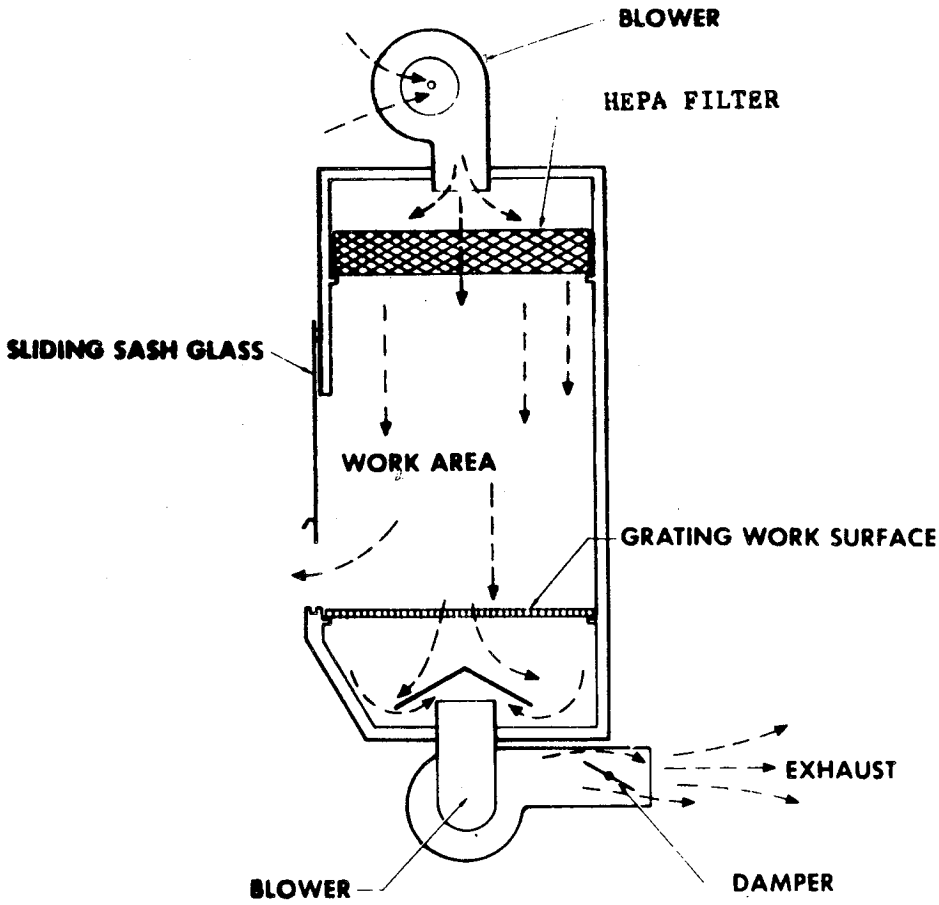


Figure 8.--Clean air exhaust hood

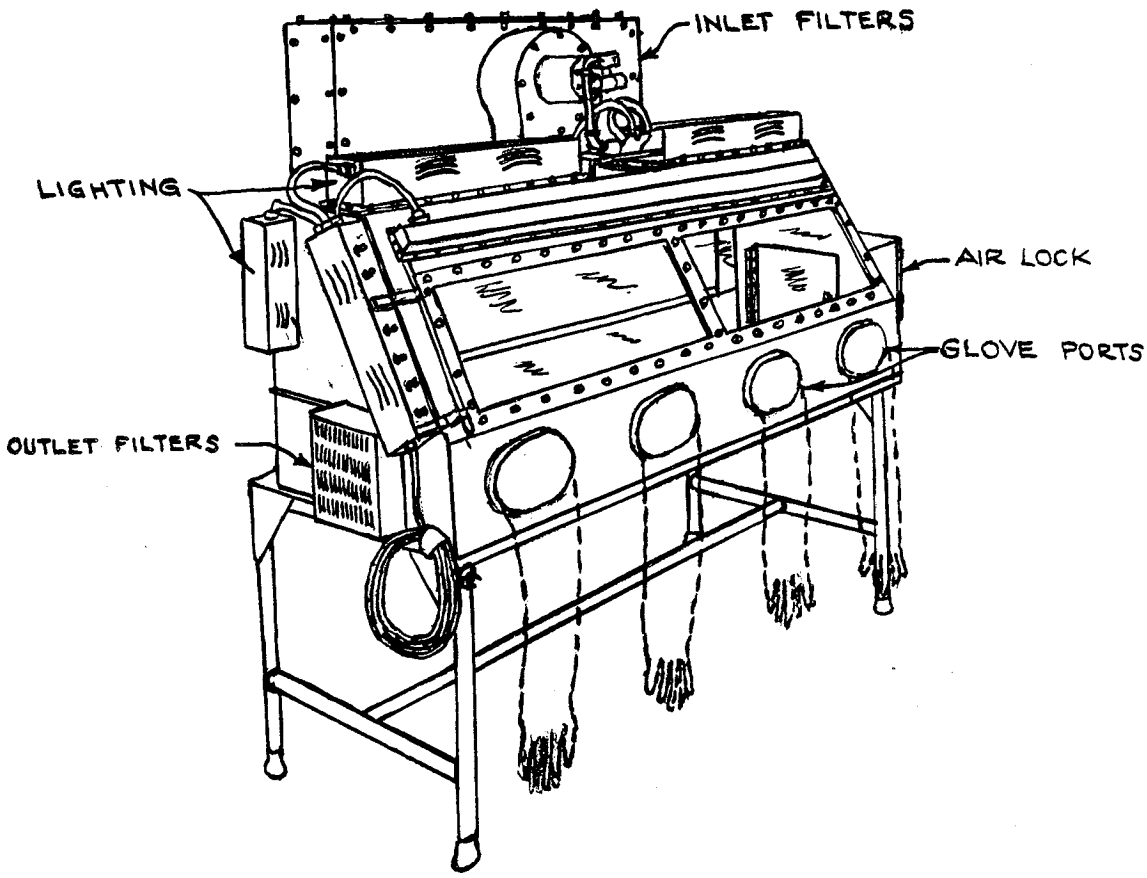


Figure 9.--Microbial barrier system

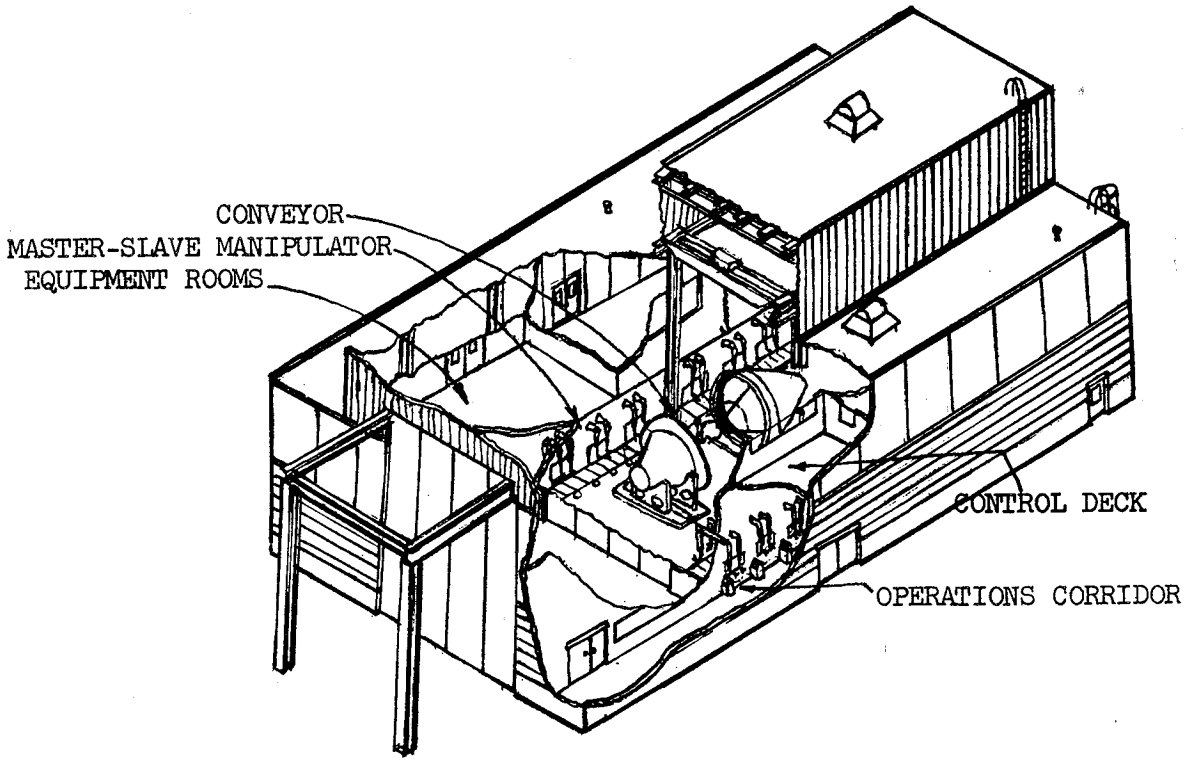


Figure 10.--Sterile room with remotely controlled operations

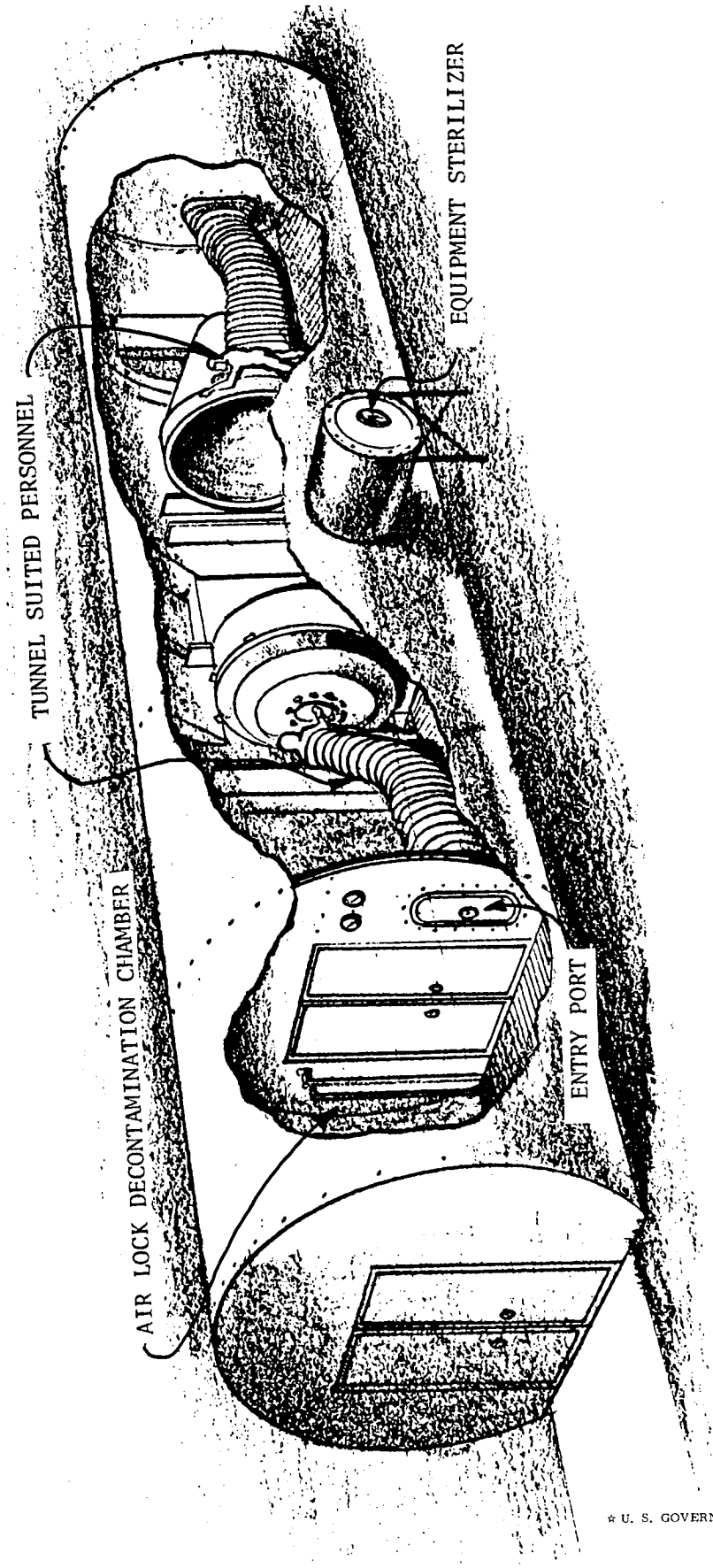


Figure 11. --Sterile room with tunnel suited personnel

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